CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2005 –4/30/2005

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Labeling Over-the-Counter Human Drug Products; Questions and Answers	OTC Draft	Level 1	1/13/2005	New
Nonclinical Safety Evaluation of Drug Combinations	Pharmacology Toxicology Draft	Level 1	1/26/2005	New
Abbreviated New Drug Applications: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	1/31/2005	New
S8 Immunotoxicity Studies for Human Pharmaceuticals	ICH Safety Draft	Level 1	2/8/2005	New
Clinical Lactation Studies-Study Design, Data Analysis, and Recommendations for Labeling	Clinical Medical Draft	Level 1	2/8/2005	New
Q8 Pharmaceutical Development	ICH Quality Draft	Level 1	2/9/2005	New
Internal Radioactive Contamination-Development of Decorporation Agents	Clinical Medical Draft	Level 1	2/15/2005	New
E2B(M) Questions and Answers	ICH Efficacy	Level 2	3/9/2005	Revised
Centralized IRB Review Proceedings in Multicenter Clinical Trials	Procedural Draft	Level 1	3/28/2005	New
Systemic Lupus Erythematosus-Developing Drugs for Treatment	Clinical Medical Draft	Level 1	3/29/2005	New

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Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics	Clinical Medical Draft	Level 1	4/4/2005	New
Exploratory IND Studies	Pharmacology Toxicology Draft	Level 1	4/14/2005	New
User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief	User Fee Draft	Level 1	4/18/2005	New